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APPELLEE'S BRIEF

2012-1131

**In the
United States Court of Appeals
For The Federal Circuit**

FILED
U.S. COURT OF APPEALS FOR
THE FEDERAL CIRCUIT

JUN 29 2012

HOFFMANN-LA ROCHE INC.,

Plaintiff-Appellant

JAN HORN
CLERK

v.

TEVA PHARMACEUTICALS USA, INC. and
TEVA PHARMACEUTICAL INDUSTRIES, LTD.,
Defendants-Appellees.

Appeal from the United States District Court
for the District of New Jersey in Case No. 09-CV-5283,
Judge Esther Salas.

**BRIEF OF DEFENDANTS-APPELLEES
TEVA PHARMACEUTICALS USA, INC. AND
TEVA PHARMACEUTICAL INDUSTRIES, LTD.**

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Dated: June 29, 2012

Form 9

FORM 9. Certificate of Interest

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

HOFFMANN-LA ROCHE

v. TEVA PHARMA

No. 2012-1131

CERTIFICATE OF INTEREST

Counsel for the (petitioner) (appellant) (respondent) (appellee) (amicus) (name of party)

Appellee Teva Pharmaceuticals USA, Inc., et al certifies the following (use "None" if applicable; use extra sheets if necessary):

1. The full name of every party or amicus represented by me is:

Teva Pharmaceuticals USA, Inc.

Teva Pharmaceutical Industries Ltd.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

Teva Pharmaceuticals USA, Inc.

Teva Pharmaceutical Industries Ltd.

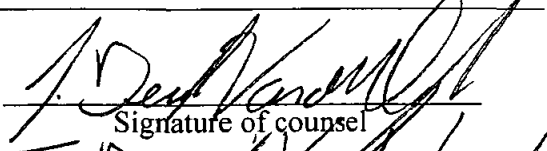
3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

Teva Pharmaceuticals USA, Inc.'s parent corporation and all publicly held corporations owning 10% or more of its stock are: Teva Pharmaceutical Industries Ltd.; Teva Pharmaceuticals Europe B.V.; Orvet UK (Majority Shareholder) and Teva Pharmaceutical Holdings Cooperative U.A. (Minority Shareholder), the latter of which is owned by IVAX LLC which is owned by Teva Pharmaceuticals USA, Inc. Teva Pharmaceutical Industries Ltd. has no parent corporation and no publicly held corporation owns 10% or more of its stock.

4. ☒ The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

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June 29, 2012
Date


Signature of counsel
J. Derek Vandenburg
Printed name of counsel

Please Note: All questions must be answered

cc: Brian D. Coggio, Esq.

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ABBREVIATIONS APPEARING IN THE BRIEF

Teva adopts herein the abbreviations used in Roche-Nutley's opening Brief.

The following additional abbreviations are also employed in this Brief:

- | | | |
|-------------------------------|---|--|
| The 1982 Regulations | - | The 1982 "Regulations of Handling Employees Inventions" that Roche Nutley has asserted controlled the inventors' obligation to assign to Nippon Roche. (A568-570.) |
| The Post-Complaint Assignment | - | The March 7, 2011 Assignment of the invention of the '949 patent from Roche Basel to Roche Nutley. (A5339.) |

I. STATEMENT OF RELATED CASES

This action is related to *Hoffmann-La Roche Inc. v. Teva Pharmaceuticals, Inc., et al.*, 11-cv-3635 (D.N.J.); *Hoffmann-La Roche Inc. v. Roxane Labs. Inc., et al.*, 2:09-cv-06335 (D.N.J.); *Hoffmann-La Roche Inc. v. Roxane Labs. Inc., et al.*, 11-cv-03637 (D.N.J.); *Hoffmann-La Roche Inc. v. Accord Healthcare, Inc., et al.*, No. 2:11-cv-01192 (D.N.J.); *Hoffmann-La Roche Inc. v. Accord Healthcare, Inc., et al.*, No. 2:11-cv-3363 (D.N.J.); *Hoffmann-La Roche Inc. v. Mylan Inc., et al.*, No. 2:09-cv-01692 (D.N.J); and *Hoffmann-La Roche Inc. v. Mylan Inc., et al.*, No. 2:11-cv-3276 (D.N.J).

II. STATEMENT OF THE ISSUES

Roche Nutley incorrectly states the issues on appeal. Correctly stated, the issues are as follows:

1. Did the district court correctly conclude that Roche Nutley failed to prove a chain of title from the inventors to Roche Nutley that gave Roche Nutley legal title to the '949 patent prior to its filing of the present suit against Teva?
2. Having found that Roche Nutley lacked standing at the time it filed suit, did the district court abuse its discretion in dismissing the case with prejudice?

III. STATEMENT OF THE CASE

Roche Nutley's Statement of the Case is both argumentative and incomplete.

Roche Nutley sued Teva for infringing the '949 patent after Teva filed an ANDA seeking FDA approval for a generic version of Xeloda,[®] the active ingredient of which is capecitabine. The '949 patent is one of two patents listed in the Orange Book for Xeloda.[®] The '949 patent claims capecitabine specifically by name, while the other, earlier patent, U.S. Patent No. 4,966,891 ("the '891 patent"), claims a group of compounds that includes capecitabine. Roche Nutley applied to the Patent Office for an extension of the term of the earlier '891 patent, telling the Patent Office that the claims of the '891 patent cover capecitabine. Roche Nutley used the '891 patent to prevent others from marketing generic capecitabine since Roche Nutley first launched capecitabine in 1998 until its expiration in January of 2011.

In an effort to continue its monopoly beyond the expiration of the '891 patent, Roche Nutley sued Teva, Mylan, Roxane and Accord for infringement of the '949 patent. The suit against Teva was filed on October 16, 2009. In response, Teva asserted that the '949 patent is invalid as anticipated by the '891 patent and is invalid for obviousness and obviousness-type double patenting.

On April 21, 2011, Mylan moved to dismiss for lack of subject matter jurisdiction on the grounds that Roche Nutley did not own the '949 patent at the

time suit was filed against it. Teva and Roxane moved to dismiss on May 12, 2011 on the same basis. In its opposition brief, Roche Nutley presented three different chain of title theories in an effort to try to prove it owned the '949 patent when it filed suit. At the consolidated hearing on the motion held on July 22, 2011, Roche Nutley presented five chain-of-title theories, including two that were not offered in its brief.

In a thorough opinion dated December 2, 2011, the District Court granted the Defendants' motion to dismiss, concluding that, under any of the theories advocated by Roche Nutley, it failed to show that it owned the '949 patent at the time it filed suit. Roche Nutley appealed.

IV. STATEMENT OF THE FACTS

Roche Nutley's argumentative Statement of the Facts ignores key facts relating to the inventors' obligations to transfer invention rights and mischaracterizes the agreements between the various Roche entities. The following is an accurate description of the agreements and assignments governing the transfer of rights to the '949 patent.

A. The Transfer From The Inventors

Roche Nutley asserts that capecitabine, the compound that is claimed in the '949 patent, was invented on November 5, 1991 when it was first synthesized by Motohiro Arasaki, one of the seven named inventors of the '949 patent. (Roche's Br. at 24-25.) At the time capecitabine was synthesized in 1991, Mr. Arasaki and the other co-inventors were all employees of Nippon Roche, a Japanese corporation. (*Id.*; A5821 at 6:24-8:23; 9:18-21; *see* A5840 at 8:1-3.)

In the district court, Roche Nutley asserted that rights to inventions made by employees of Nippon Roche were governed by the 1982 Regulations. (A6; A9; A10; A4765-67; A4769; A568-570.) According to the translation provided by Roche Nutley, the 1982 Regulations stated that Nippon Roche "shall succeed the right to obtain a patent concerning the said Employee's Service Invention." (A568 at Article 2 ¶ 1.) At the motion to dismiss hearing, Roche Nutley admitted that the 1982 Regulations did not constitute a present assignment of future patent rights

and did not automatically transfer any ownership rights to the invention from the inventors to Nippon Roche. (A6 at n. 7; A5957 at 125:8-11.) Notably, Roche Nutley omits any mention of this agreement in its opening appeal brief.

The earliest document evidencing any transfer of ownership rights to the invention of the '949 patent was the October 1993 Assignment. (A5303-5304.) Rather than assign their rights to Nippon Roche as provided for in the 1982 Regulations, the seven inventors expressly assigned "all rights and title to and from the said Invention and from the said application(s) in all countries of the world" to Roche Basel. (A5303.)

B. The 1969 Agreement Between Nippon Roche and Roche Basel

The 1969 Agreement between Nippon Roche and Roche Basel provided that:

Nippon [Roche] agrees to enter into invention agreements with all employees who work in capacities in which they might reasonably be expected to make inventions of value to Nippon [Roche] or Roche [Basel], in a form of agreement to be approved by Roche [Basel] or to establish the bylaw which is required under Japanese Patent Law where Nippon [Roche] acquires any invention made by any employee based upon or in relation to his duties.

(A576-577 at ¶ 2; A583.) The 1969 Agreement further provided that:

Nippon [Roche] agrees that all inventions made or conceived by such employees, alone or jointly with others, during the respective periods of their employment (including any periods of authorized leave of absence) belong to Roche [Basel] and *Nippon [Roche] therefore agrees to assign such inventions to*

Roche [Basel] and to assist Roche in every proper way to obtain patents of such inventions in any or all countries.

(A576-577 at ¶ 2 (emphasis added).) Based on the above language, the 1969 Agreement was not a present assignment of future invention rights, but rather was merely a promise to assign rights in the future.

No evidence has been presented that Nippon Roche ever executed a transfer of ownership rights to the invention of the '949 patent to Roche Basel or any other entity.

C. The Agreements Between Roche Basel and Roche Nutley

Three agreements between Roche Basel and Roche Nutley are relevant here: the 1963 Agreement, the 1992 Agreement and the Post-Complaint Assignment. The determination of which of these Agreement governs the ownership rights to the '949 patent is of critical importance to this appeal.

1. The 1992 Agreement

At the time of the October 1993 Assignment from the inventors to Roche Basel, the only agreement in place between Roche Basel and Roche Nutley concerning ownership of inventions and patents was the 1992 Agreement. (A605-A617.)

The 1992 Agreement took into account the fact that Roche Basel and Roche Nutley might acquire intellectual property rights through their own development

efforts or by transfer from a third party such as Nippon Roche. Thus, the 1992 Agreement defined “Developed Technology” as:

any patents, patent applications, new drug applications, product license applications, inventions, formulae, specifications, protocols, processes, designs, patterns, research related software, trade secrets, know how, data, information, copyrights of technical materials, or other similar property rights (a) that are generated, developed, or first reduced to practice by, or on behalf of, either or both of the Parties pursuant to this Agreement, or (b) ***that relate to Products and are acquired by Transfer*** by, or on behalf of, either or both of the Parties, but only if such acquisition results in substantial direct benefits to both Parties. Each such right shall constitute an item of Developed Technology.

(A607 at Section 1.7 (emphasis added).) The 1992 Agreement defined “Product” to mean “any Medical Product, Consumer Product, or Diagnostic Product that has been manufactured by, or on behalf of, a Party or an Affiliate or, if the subject of research and development, might be manufactured by, or on behalf of, a Party or an Affiliate in the future.” (A607-608 at Section 1.13.) The 1992 Agreement defined “Transfer” as “with respect to an intangible, its transfer by sale, exchange, ***assignment***, license, or any other means.” (A609 at Section 1.20 (emphasis added).)

Relative to ownership of inventions and patents, the 1992 Agreement provided:

Each party shall be entitled to exclusive ownership within its respective geographic market of all items of Developed Technology. The geographic market of [Roche Nutley] shall be the United States, and that of Roche [Basel] shall be the remainder of the world outside the United States.

(A612 at Section 4.1.) Both on appeal and at the district court, Roche conceded that this language from the 1992 Agreement did not constitute a present assignment of future inventions or patents, and did not provide for an automatic transfer of ownership rights between Roche Basel and Roche Nutley. (Roche's Br. at 21; A5852 at 20:16-25.) Rather, it merely created a future obligation to assign such ownership rights.

Finally, the 1992 Agreement expressly stated that it "supersedes, replaces and revokes all prior Agreements between the Parties, including the Research Agreement entered into on January 25, 1963." (A616 at Section 8.2.)

2. The 1963 Agreement

The 1963 Agreement between the Roche Basel and Roche Nutley was the predecessor of the 1992 Agreement. (A602-603.) It provided for an exchange of information between Roche Basel and Roche Nutley, which information was defined as "Research Results:"

Roche Basel and Roche Nutley will each maintain and develop its research and laboratory facilities and will carry on its research and development programs in full cooperation with each other. To this end there shall be a full exchange between them of *information* regarding their respective research activities including full *information* regarding all inventions,

discoveries, formulae processes, manufacturing secrets, technical, pharmacological and clinical data, improvements and developments made or acquired in any field (*hereinafter referred to as "Research Results"*).

(A602 at ¶ 2 (emphasis added).) The agreement explicitly distinguished the "Research Results" (i.e., information) from "property rights" in the Research Results:

[a]ll Research Results, whether heretofore developed pursuant to prior Research Agreements of 1941 or 1950, or hereafter developed, and all property rights therein belong and shall belong to Roche Nutley within the United States of America and to Roche Basel within all other countries in the world.

(A602-603 at ¶ 3.) The 1963 Agreement also separately governed patent rights:

Roche Basel has heretofore assigned and hereby assigns all its rights in existing patents and patent applications for the United States of America and all its rights in future patents and patent applications for the United States of America to Roche Nutley, and Roche Nutley has heretofore assigned and hereby assigns all its rights in existing patents and patent applications for all other countries of the world and for all its rights in future patents and patent applications for all other countries of the world to Roche Basel.

(*Id.*)

Like the subsequent 1992 Agreement, the 1963 Agreement recognized that Roche Basel and Roche Nutley would develop inventions themselves and also might acquire them from other companies. Thus, as part of the definition of "Research Results," the 1963 Agreement refers to inventions, discoveries, etc. that are "made or acquired in any field." (A602 at ¶ 2.)

Finally, the 1963 Agreement states that “[t]ermination of this agreement shall not affect any rights or obligations of the parties hereunder with respect to Research Results existing prior to such termination.” (A603 at ¶ 5.)

3. The Post-Complaint Assignment

Notably missing from Roche Nutley’s opening brief is any mention of the March 7, 2011 Post-Complaint assignment of the invention from Roche Basel to Roche Nutley. (A5339.) The Post-Complaint Assignment transferred all “right, title and interest, if any, within the United States of America” in the invention of the ‘949 patent from Roche Basel to Roche Nutley. (*Id.*) The Post-Complaint Assignment was executed more than one year after the complaint in the present action. (*Id.*)

Roche has provided no explanation in the district court as to why this assignment was necessary if in fact Roche Nutley owned the patent by virtue of Roche Nutley’s chain of title theory. (A5928-5929 at 96:1-97:21.) The Post-Complaint Assignment was executed *before* the first motion to dismiss for lack of standing was filed in the *Roche v. Mylan* action, on April 21, 2011. (A52.) Accordingly, Roche Nutley did not execute the Post-Complaint Assignment in response to the motion. Rather, Roche Nutley apparently recognized there was a problem with the title to the invention and executed the Post-Complaint Assignment to fix it.

D. Summary of Agreements

For the convenience of the Court, the relevant agreements discussed above are summarized in the following table:

Agreement	Parties	Relevant Provisions
The 1982 Regulations (A568-70)	Inventors and Nippon Roche	Nippon Roche “shall succeed the right to obtain a patent.”
The 1969 Agreement (A576-78)	Nippon Roche and Roche Basel	“Nippon [Roche] agrees that all inventions made or conceived by such employees . . . belong to Roche [Basel] and Nippon [Roche] therefore agrees to assign such.”
The 1963 Agreement (A602-03)	Roche Basel and Roche Nutley	Research Results and property rights therein belong to Roche Nutley in the US and Roche Basel everywhere else. All rights in patents belong to Roche Nutley in the US and Roche Basel everywhere else. Termination does not affect Research Results and the parties’ rights therein.
The 1992 Agreement (A605-17)	Roche Basel and Roche Nutley	Agreement “supersedes, replaces and revokes 1963 Agreement.” Each Party “shall be entitled to exclusive ownership within its respective geographic market of all items of Developed Technology.”
The 1993 Assignment (A5303-04)	Inventors and Roche Basel	Inventors “sold, assigned and transferred all rights and title to and from the said invention and from the said application(s) in all countries of the world” to Roche Basel.

The Post-Complaint Assignment (A5339)	Roche Basel and Roche Nutley	Roche Basel assigned “all of our right, title and interest, if any within the United States . . . in and to the invention described and claimed in [the application], . . . which issued as the ‘949 patent” to Roche Nutley.
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V. SUMMARY OF ARGUMENT

The District Court correctly held that Roche Nutley lacked title to the '949 patent when it sued Teva. Roche Nutley's theory on appeal is based on the premise that Roche Basel received equitable title to the subject matter of the '949 patent from Nippon Roche at the time of the alleged invention in 1991. However, neither the alleged agreement between the inventors and Nippon Roche arising out of the 1982 Regulations nor the 1969 Agreement between Nippon Roche and Roche Basel constituted a present assignment of future intellectual property rights. Rather, at most those agreements constituted mere agreements to assign in the future. An agreement to assign intellectual property rights is insufficient to transfer any ownership interest. Therefore, the first time that Roche Basel received any ownership interest in the subject matter of the '949 patent was when the inventors executed a written assignment in October of 1993.

Because the inventors did not assign their ownership rights until 1993, the transfer of rights from Roche Basel to Roche Nutley is governed by the 1992 Agreement, not the 1963 Agreement. In this regard, the so-called "survival clause" of the 1963 Agreement relied on by Roche Nutley is inapplicable for at least two reasons. One, as the District Court correctly found, patent rights are not "Research Results" as defined in the 1963 Agreement and, therefore, the so-called "survival clause" is inapplicable.

Two, even if Roche Nutley's contrary interpretation of the 1963 Agreement were accepted, the definition of "Research Results" in the 1963 Agreement was nonetheless limited to "inventions...*made* or *acquired* in any field." Neither of the parties to the 1963 Agreement (Roche Basel and Roche Nutley) "made" the invention of the '949 patent. While Roche Basel did eventually "acquire" the invention of the '949 patent, it did so only in October of 1993, *after* the 1963 Agreement was revoked and replaced by the 1992 Agreement. Thus, even under Roche Nutley's reading of the 1963 Agreement, the alleged capecitabine invention does not constitute a "Research Result" under that Agreement.

That the transfer of rights from Roche Basel to Roche Nutley is controlled by the 1992 Agreement, not the 1963 Agreement, is fatal to Roche Nutley's standing argument. It is undisputed that the 1992 Agreement did not contain automatic assignment language, but rather contained a mere promise to assign ownership rights in the future. It is also undisputed that Roche Basel did not assign its ownership rights in the '949 patent to Roche Nutley until March of 2011, after the present lawsuit was filed. Therefore, the District Court correctly dismissed for lack of standing because Roche Nutley did not own the patent at the time suit was filed.

Finally, the District Court acted within its discretion and within its inherent power to manage its docket by dismissing the complaint with prejudice.

VI. ARGUMENT

A. The Law of Ownership, Assignment and Agreements to Assign

As an initial matter, rights in an invention belong to the inventor. *Bd. of Trs. v. Roche Molecular Sys.*, 131 S. Ct. 2188, 2195 (2011). “[U]nless there is an agreement to the contrary, an employer does not have rights in an invention which is the original conception of the employee alone. Such an invention remains the property of him who conceived it. In most circumstances, an inventor must expressly grant his rights in an invention to his employer if the employer is to obtain those rights.” *Id.* (internal citations and quotations omitted).

Ownership rights in inventions, patents and patent applications can be assigned. *Id.* When an entity assigns its ownership rights in an existing invention, patent or patent application, legal title passes from the assignor to the assignee. *See Crown Die & Tool Co. v. Nye Tool & Machine Works*, 261 U.S. 24, 40-41 (1923) (holding that an assignee has legal title sufficient to sue for infringement). Assignments of patents and patent applications must be in writing. 35 U.S.C. § 261.

Ownership rights in inventions, patents and patent applications can also be assigned prior to their coming into existence. *Abraxis Bioscience, Inc. v. Navinta LLC*, 625 F.3d 1359, 1364 (Fed. Cir. 2010). In this regard, however, it is important to distinguish between a present assignment of a future intellectual property right

and a mere agreement to assign rights in the future. An agreement that “hereby assigns” future inventions or patents is a present assignment of future intellectual property. *Speedplay, Inc. v. Bebo, Inc.*, 211 F.3d 1245, 1253 (Fed. Cir. 2000). In that circumstance, the assignee immediately receives equitable title to the invention and any intellectual property rights issuing thereon. *Bd. of Trs. of the Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.*, 583 F.3d 832, 841-42 (Fed. Cir. 2009), *aff’d*, 131 S. Ct. 2188 (2011); *FilmTec Corp. v. Allied-Signal Inc.*, 939 F.2d 1568, 1572 (Fed. Cir. 1991). Moreover, once the intellectual property right comes into existence (i.e., a patent application is filed or a patent issues), the assignee’s equitable title automatically converts to legal title without the need to execute any further documentation. *Bd. of Trs. of the Leland Stanford Junior Univ.*, 583 F.3d at 842.

In contrast, an agreement “to assign” future inventions or patents is merely an agreement to assign rights in the future. *Id.* at 841. Such an agreement is not, in itself, an assignment and, therefore, does not transfer either legal or equitable title. Thus, for example, in *Bd. of Trs. of the Leland Stanford Junior Univ.*, this Court held that the party receiving an agreement to assign “did not immediately gain title” to the invention, while the party that subsequently received an assignment of an expectant interest “immediately gained equitable title.” *Id.* at 841-42; *see also IpVenture, Inc. v. Prostar Computer, Inc.*, 503 F.3d 1324, 1327

(Fed. Cir. 2007) (employer “never had an interest” in employee’s patent, despite employment agreement containing an agreement to assign). While this Court has suggested that the party receiving an agreement to assign “might [gain] certain equitable rights” against the promissor, this Court has not described those possible equitable rights as an ownership interest nor equated them with “equitable title.” See *Bd. of Trs. of the Leland Stanford Junior Univ.*, 583 F.3d at 841; see also *Arachnid, Inc. v. Merit Indus., Inc.*, 939 F.2d 1574, 1581 (Fed. Cir. 1991).

The determination of whether contractual language constitutes a present assignment of future rights or an agreement to assign rights in future is resolved as a matter of Federal Circuit law. *Bd. of Trs. of the Leland Stanford Junior Univ.*, 583 F.3d at 841.

B. Roche Basel Acquired No Ownership Interest in the Alleged Invention of the ‘949 Patent Until October 1993

Before determining whether legal title in the ‘949 patent transferred from Roche Basel to Roche Nutley prior to filing suit, it is necessary to determine what ownership interest Roche Basel obtained in the subject matter of the ‘949 patent, and when. Because neither the inventors nor Nippon Roche executed a present assignment of future intellectual property rights, no ownership interest transferred to Roche Basel until the inventors’ written assignment was executed in October 1993.

1. Prior to October 1993, All Ownership Interest in the Purported Invention Remained With the Inventors

Roche Nutley argues that Roche Basel acquired “equitable title” to the invention when capecitabine was made on November 5, 1991 pursuant to the 1969 Agreement between Nippon Roche and Roche Basel. (Roche’s Br. at 25-26.) But Nippon Roche had no ownership interest to transfer to Roche Basel unless the Nippon Roche employees/inventors first transferred their ownership interest to Nippon Roche. Roche Nutley’s opening brief is devoid of any argument, much less evidence, that the inventors conveyed any ownership interest in the invention to Nippon Roche.

In the district court, Roche Nutley attempted to rely on Nippon Roche’s “Regulations of Handling Employees Inventions.” (A6; A9; A10; A4765-67; A4769; A568-570.) Even assuming that the inventors were contractually bound by these Regulations, however, they merely state that “[Nippon Roche] shall succeed the right to obtain a patent concerning the said Employee’s Service Invention.” (A568 at Article 2 ¶ 1.) ***Roche Nutley admitted in the district court that this language did not constitute a present assignment of future rights.*** (A6 at n.7; A5957 at 125:8-11.) Roche is bound by this concession on appeal. *See Berckelely Inv. Group, Ltd. v. Colkitt*, 455 F.3d 195, 211 n.20 (3d Cir. 2006) (“Judicial admissions are concessions in pleadings or briefs that bind the party who makes them.”); *Glick v. White Motor Co.*, 458 F.2d 1287, 1291 (3d Cir. 1972) (“[J]udicial

admissions are binding for the purpose of the case in which the admissions are made including appeals.”) Absent a present transfer of future rights, the Regulations constituted at best a mere promise to assign, which was insufficient to transfer any ownership rights in the invention or resulting patents. *See Bd of Trs. of Leland Stanford Junior Univ.*, 583 F.3d at 841-42 (holding that a party “did not immediately gain title” to an invention as a result of an agreement to assign). Therefore, the inventors did not convey any ownership rights to Nippon Roche.

The only evidence of a transfer of ownership rights by the inventors was the October 1993 Assignment from the inventors to Roche Basel. (A5303-04.) Thus, that is the date that Roche Basel first obtained any ownership interest in the subject matter of the ‘949 patent.

2. Roche Basel Acquired No Ownership Rights to the ‘949 Patent Via the 1969 Agreement

Without a transfer of rights to Nippon Roche, it is irrelevant what transfer provisions were contained in the 1969 Agreement between Nippon Roche and Roche Basel. Since Nippon Roche never obtained any ownership interest in the invention of the ‘949 patent, Nippon Roche had no such rights to transfer to Roche Basel in 1991 or any other time.

In this regard, the *FilmTec* case cited by Roche Nutley is relevant. In that case, the inventor was employed by MRI. *FilmTec*, 939 F.2d at 1571. A contract between MRI and the government included language constituting a present

assignment of future invention rights from MRI to the government. *Id.* at 1570. MRI also warranted that it would obligate inventors to assign their rights to MRI. *Id.* at 1571. This Court held if the inventor had granted ownership of inventions made during his employment to MRI, then the invention would belong to the government as a result of the automatic assignment provision from MRI to the government. *Id.* at 1572. However, the Court also recognized that if the inventor had not granted rights to inventions to his employer, then the inventor retained ownership and could later assign those rights to a party other than MRI. *Id.* In other words, the conveyance of ownership from the inventor to MRI was necessary for the government to obtain title to the invention from MRI. *Id.* at 1573. The same is true here. Regardless of the contractual arrangement between Nippon Roche and Roche Basel, Nippon Roche could not transfer any ownership to Roche Basel because it never obtained any ownership rights from the inventors. *See also Abraxis*, 625 F.3d at 1365 (the purported assignor “could not assign the patents because it did not possess their titles”).

A second flaw in Roche Nutley’s argument is that, unlike the agreement between MRI and the government in *FilmTec*, the 1969 Agreement between Nippon Roche and Roche Basel did not contain automatic assignment language. Rather, Nippon Roche merely agreed to a future assignment of inventions made by its employees to Roche Basel:

Nippon [Roche] agrees that all inventions made or conceived by such employees . . . belong to Roche [Basel] and ***Nippon [Roche] therefore agrees to assign such inventions to Roche [Basel]*** and to assist Roche [Basel] in every proper way to obtain patents of such inventions in any or all countries.

(A576-577 at ¶ 2 (emphasis added).) As Roche Nutley appears to concede in its appeal brief (Roche's Br. at 26), this language is not an automatic assignment.

Rather, this language is a promise to assign. As previously discussed, a promise to assign does not transfer any ownership rights, equitable or legal. *Bd. of Trs. of the Leland Stanford Junior Univ.*, 583 F.3d at 841. Thus, even if the inventors had transferred ownership rights to Nippon Roche (which they did not), there was no subsequent assignment of ownership rights by Nippon Roche to Roche Basel.

In this regard, Roche wrongly characterizes what Roche Basel received from Nippon Roche via the 1969 Agreement as "equitable title." (E.g., Roche's Br. at 16, 24, 26.) "Equitable title" is what an entity obtains as a result of a present assignment of future intellectual property rights, prior to the creation of those rights. *Filmtec*, 939 F.2d at 1572 ("An assignment of an expectant interest can be a valid assignment. In such a situation, the assignee holds at most an equitable title." (internal citations omitted)). Neither the inventors' agreement with Nippon Roche nor Nippon Roche's 1969 Agreement with Roche Basel was a present assignment of future rights. Thus, neither Nippon Roche nor Roche Basel received equitable title at any time; they merely received the right to compel an assignment

of title. The first time that title (either equitable or legal) transferred was in 1993 when the inventors executed the October 1993 Assignment.

C. When the Inventors Assigned the Invention to Roche Basel in October 1993, Roche Nutley's Rights to the '949 Patent Were Not Governed by the 1963 Agreement

By the time the inventors assigned their ownership rights to Roche Basel in October 1993, the 1963 Agreement between Roche Basel and Roche Nutley was expressly “supersede[d], replace[d] and revoke[d]” by the 1992 Agreement. (A616 at Section 8.2.) Roche Nutley argues that, because of the so-called “survival clause” of the 1963 Agreement, ownership of the ‘949 patent nonetheless transferred from Roche Basel to Roche Nutley pursuant to the 1963 Agreement. (Roche’s Br. at 28-29.)

This argument fails for at least two reasons. One, as the District Court correctly held, patent rights are not “Research Results” under the 1963 Agreement and, therefore, are not the subject of the so-called “survival clause.” Two, because the alleged invention of the ‘949 patent was not made by Roche Basel or Roche Nutley, but rather was acquired in 1993 from employees of a separate company, it was not a “Research Result” even under Roche Nutley’s interpretation of the 1963 Agreement.

1. Patent Rights Were Not “Research Results” Under the 1963 Agreement

In its appeal brief, Roche Nutley repeatedly asserts that “Research Results” under the 1963 Agreement is defined to include inventions and discoveries. (Roche’s Br. at 12, 17-18, 20, 27.) Roche Nutley even goes so far as to substitute “inventions, discoveries” for “Research Results” in purporting to quote other portions of the 1963 Agreement. (See Roche’s Br. at 14.) This is mis-reading of the 1963 Agreement. As the District Court found, the 1963 Agreement defines “Research Results” as “*information regarding* [Roche Basel’s and Roche Nutley’s] respective research activities including full *information regarding* all inventions, discoveries, formulae, processes, manufacturing secrets, technical, pharmacological and clinical data, improvement and developments made or acquired in any field.” (A6-A7, *quoting* A602 at ¶ 2.)

Moreover, regardless of whether “Research Results” refers to “information” or to “inventions,” the 1963 Agreement clearly and intentionally treated patent rights separately from “Research Results.” In Paragraph 3, the 1963 Agreement first addresses the division of “property rights” regarding Research Results:

“All Research Results . . . and all property rights therein belong and shall belong to Roche Nutley within the United States and to Roche Basle within all other countries in the world.

(A602-603 at ¶ 3.) The next sentence of Paragraph 3 then goes on to separately discuss patent rights:

Roche Basel has heretofore assigned and hereby assigns all of its rights in existing patents and patent applications for the United States of America and all its rights in future patents and patent applications for the United States of America to Roche Nutley. . . .”

(*Id.*) Paragraph 4 likewise treats patent rights separate from Research Results:

“[T]he exchange or assignment hereunder of any Research Results *or* patent rights acquired by either party hereto from a third party...” (A603 at ¶4.) Paragraphs 3 and 4 make no sense if the term “Research Results” itself includes patent rights. As the District Court concluded, reading the agreement as a whole and giving meaning to the entire agreement, patent rights are not “Research Results” as defined in the 1963 Agreement. Therefore, the so-called “survival clause” that relates to Research Results does not encompass patent rights.

Roche Nutley alternatively argues that the 1963 Agreement applies because the so-called “survival clause” extends not just to Research Results, but also to the “rights and obligations of the parties” with respect to Research Results. (Roche’s Br. at 20.) Roche Nutley argues that “rights and obligations of the parties” in that clause includes patent rights. (*Id.* at 28-29.)

The problem with this argument, however, is that, as discussed above, Roche Basel did not obtain any ownership rights in the ‘949 patent, legal or equitable, until the October 1993 Assignment. Thus, at the time the 1963 Agreement was terminated in 1992, Roche Nutley did not have any patent rights in the subject matter of the ‘949 patent that could be subject to the survival clause of the 1963

Agreement. Therefore, patent rights to capecitabine do not fall within the so-called “survival clause” of the 1963 Agreement and are not governed by the 1963 Agreement.

2. **Even Under Roche’s Interpretation of the 1963 Agreement, the Capecitabine Invention Was Not a “Research Result” Because It Was Not Made or Acquired By Roche Basel or Roche Nutley During the Term of the Agreement**

While not addressed by the District Court, there is a second reason why the survival clause of the 1963 Agreement does not apply to the ‘949 patent: the definition of “Research Results” requires that an invention be “made” or “acquired” by Roche Basel or Roche Nutley:

[T]here shall be a full exchange between [Roche Basel and Roche Nutley] of information regarding *their respective research activities* including full information regarding all inventions, discoveries, formulae processes, manufacturing secrets, technical, pharmacological and clinical data, improvements and developments *made or acquired* in any field (hereinafter referred to as “Research Results”).

(A602 at ¶ 2.) While the above language from the 1963 Agreement does not expressly state “made or acquired *by Roche Basel or Roche Nutley*,” that is the only interpretation of the above-quoted language that makes sense. First, the entire phrase beginning with “inventions, discoveries,...” is written to be a subset of the earlier phrase “*their* respective research activities.” The word “their” refers to Roche Basel and Roche Nutley. Second, the 1963 Agreement was an agreement between Roche Nutley and Roche Basel; it would be absurd to expect that Roche

Nutley and Roche Basel nonetheless intended the agreement to apply to *any* invention made by *any* company in *any* field *anywhere* in the world. Finally, if the parties to the Agreement had intended such an absurdly broad definition, then there would be no need to include the subsequent words “or acquired,” which would be superfluous.

In its brief, Roche Nutley simplistically asserts that the capecitabine invention became a “Research Result” in 1991 because that is when capecitabine was allegedly first “made.” (Roche’s Br. at 24-25.) That assertion, however, ignores the fact that capecitabine was not “made” by employees of either Roche Basel or Roche Nutley. Rather, the inventors who synthesized capecitabine in 1991 were employees of a third party, Nippon Roche. As such, the synthesis of capecitabine in 1991 was insufficient to bring it within the definition of “Research Results” under the 1963 Agreement. This is true regardless of whether, as the District Court found, “Research Results” refers to “information” or, as Roche Nutley argues, “Research Results” refers to directly to “inventions, discoveries,” etc.

Roche Basel did eventually “acquire” the capecitabine invention; however, that acquisition did not occur until October 1993 when the inventors executed the October 1993 Assignment. At that time, the 1963 Agreement was no longer in place because it had been superseded, revoked and replaced by the 1992

Agreement effective January 1, 1992. (A616 at Sections 8.1, 8.2.) Accordingly, capecitabine cannot be found to be a “Research Result” under the 1963 Agreement and therefore, ownership of that alleged invention is not governed by the 1963 Agreement.

D. The 1992 Agreement Controlled the Rights to the ‘949 Patent And Did Not Automatically Transfer Rights To Roche Nutley

To support its contention that transfer of the ‘949 patent from Roche Basel to Roche Nutley was governed by the 1963 Agreement, Roche Nutley argues that the transfer cannot be governed by the 1992 Agreement because capecitabine was invented prior to the January 1, 1992 effective date of the 1992 Agreement.

(Roche’s Br. at 30.)

First, even if Roche Nutley were correct that transfer of the ‘949 patent was not governed by the 1992 Agreement, that would not mean that the transfer must be governed by the 1963 Agreement. Roche Nutley and Roche Basel chose to use to the language they did in the 1963 and 1992 Agreements. If those Agreements resulted in a “gap,” where certain inventions or patents are not governed by either agreement, they should blame their lawyers for drafting poor agreements. It is not, however, a basis to ignore the language of the agreements or to conclude that ownership of the ‘949 patent must be governed by the 1963 Agreement.

In fact, however, ownership of the ‘949 patent is governed by the 1992 Agreement because legal title to the ‘949 patent was transferred to Roche Basel in

October 1993 while the 1992 Agreement was in effect. Roche mistakenly argues that the 1992 Agreement only applies to inventions, patents and patent applications that are “generated, developed or first reduced to practice” pursuant to the 1992 Agreement. (Roche’s Br. at 30.) Like the prior 1963 Agreement, the 1992 Agreement covered not only inventions and patents that were developed by Roche Basel or Roche Nutley, it also covered inventions that Roche Basel or Roche Nutley *acquired* from third parties such as Nippon Roche. Section 1.7(b) of the 1992 Agreement governs patents and patent applications “that relate to Products and are acquired by Transfer . . . if such acquisition results in substantial direct benefits to both Parties” (A607 at Section 1.7(b).) Transfer is defined to mean “transfer by . . . assignment.” (A609 at Section 1.20.) Product is defined to mean products that might be manufactured by a party in the future. (A607-608 at Section 1.13.) Here, Roche Basel acquired the rights to the patent on capecitabine, a product that was later manufactured by Roche Nutley, from the inventors in October 1993, and both Roche Basel and Roche Nutley were expected to benefit from the ownership rights to the patent in their respective parts of the world. Therefore, the ‘949 patent rights are governed by Section 1.7(b) of the 1992 Agreement.

Because the 1992 Agreement controls the ownership of the ‘949 patent, Roche Nutley did not automatically acquire title to the ‘949 patent when the

inventors assigned their ownership rights to Roche Basel in October 1993. The 1992 Agreement merely states that “each party shall be entitled to exclusive ownership within its respective geographic market of all items of Developed Technology.” (A612 at Section 4.1.) This language does not indicate a present assignment of future intellectual property. Indeed, Roche conceded both in the district court and on appeal that the 1992 Agreement between Roche Basel and Roche Nutley did not automatically convey the invention from Roche Basel to Roche Nutley. (Roche’s Br. at 21; A5852 at 20:16-25.) Accordingly, the rights to the ‘949 patent transferred from the inventors to Roche Basel in October 1993 and remained with Roche Basel until March 2011 when Roche Basel assigned the ‘949 patent to Roche Nutley.

E. Roche Failed To Explain The Post-Complaint Assignment

Roche’s argument that Roche Nutley held title to the ‘949 patent when the complaint was filed is belied by Roche’s execution of the Post-Complaint Assignment and recording it in the Patent Office. Such a belated assignment is “clear recognition” that the plaintiff did not previously hold legal title and that a further document was needed to perfect transfer of legal title. *Abraxis*, 625 F.3d at 1365-66. Roche failed to provide any explanation as to the purpose of that assignment, other than that Roche was responding to the briefs in the motion to dismiss. (A5928-5929 at 96:1-97:21.) This explanation does not add up. Mylan

filed its motion to dismiss well after the date of the Post-Complaint Assignment. As such, Roche must have had some other purpose for executing the Post-Complaint Assignment. The Post-Complaint Assignment shows that Roche knew that Roche Basel did not have title to the invention when it sued Teva and attempted to fix it.

F. The District Court Employed Its Discretion To Dismiss With Prejudice

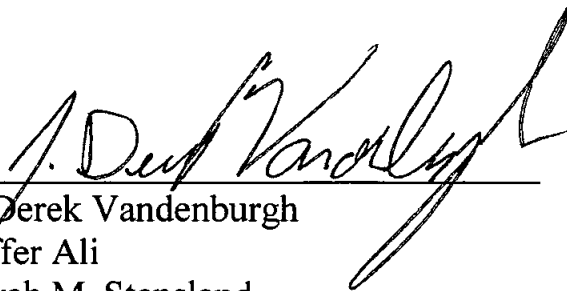
The District Court properly dismissed the case with prejudice. The Third Circuit and this Court permit a dismissal for lack of standing to be granted with prejudice. *See Tyco Healthcare Group LP v. Ethicon Endo-Surgery, Inc.*, 587 F.3d 1375, 1380 (Fed. Cir. 2009) (“Within the sound discretion of the district court is the decision of whether dismissal is with or without prejudice.”); *H.R. Techs., Inc. v. Astechologies, Inc.*, 275 F.3d 1378, 1384 (Fed. Cir. 2002) (noting that “a dismissal of a complaint for lack of standing would not normally be expected to be made with prejudice”); *Kenrich Corp. v. Miller*, 377 F.2d 312, 314 (3d Cir. 1967) (affirming a dismissal with prejudice for lack of standing). Moreover, a court has the inherent power to manage its own docket by dismissing a case with prejudice. *See Lee v. Krieg*, 227 F. App’x 146, 147 (3d Cir. 2007). Here, the District Court properly exercised its discretion and inherent power when it dismissed Roche’s case with prejudice.

Roche improperly asks this Court to render an opinion regarding the effect of the District Court's dismissal with prejudice. (Roche's Br. at 32-33.) The effect of the with-prejudice decision is not at issue here and is not properly before this Court. Therefore, the Court should disregard Roche's arguments on this point.

VII. CONCLUSION AND STATEMENT OF RELIEF SOUGHT

For the foregoing reasons the judgment of the district court should be affirmed.

June 29, 2012



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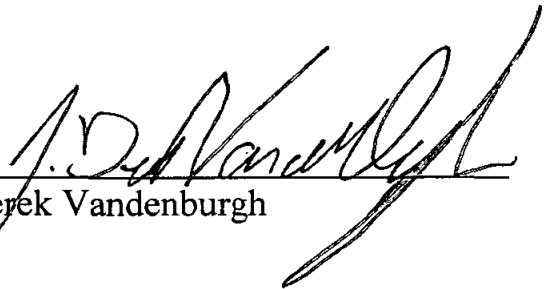
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PROOF OF SERVICE

I hereby certify that two copies of the foregoing RESPONSE BRIEF OF DEFENDANTS-APPELLEES TEVA PHARMACEUTICALS USA INC., AND TEVA PHARMACEUTICAL INDUSTRIES, LTD. were served by Federal Express on June 29, 2012 on counsel of record as follows:

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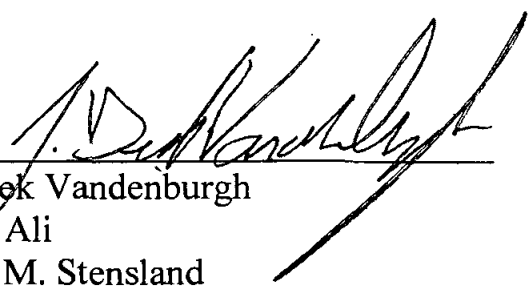


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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C), I certify that the word count of the word processing software used to prepare this brief is 6,798 words.

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